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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/242,843	11/18/1999	PAUL JARRETT		1574

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EXAMINER	
MCGARRY, SEAN	
ART UNIT	PAPER NUMBER
1635	22

DATE MAILED: 08/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/242,843	JARRETT ET AL.
	Examiner	Art Unit
	Sean McGarry	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-58* is/are pending in the application.

4a) Of the above claim(s) *51-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 37-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection and is maintained for those reasons set forth in the official action mailed 3/29/01 and 11/20/01.

The instant invention is broadly drawn to an insecticidal composition that comprises a proteinaceous pesticidal compound obtainable from Xenorhabdus nematophilus and is encoded by SEQ ID NO:1 or variants thereof which are encoded by a nucleic acid that may hybridize to SEQ ID NO:1 "under stringent conditions". SEQ ID NO: 1 is a nucleic acid sequence of almost 40kb. The specification, for example, indicates that this sequence may contain more than one protein coding sequence that may be insecticidal either alone or when presented together (see page 3, lines 10-15). The specification does not provide one in the art what the coding sequence may be within this large piece of DNA or what the sequence or structure of the protein or proteins is/are or whether there are in fact two or more proteins that may or may not be needed to provide for an insecticidal activity. The specification does not indicate from what reading frame the protein or proteins may be expressed from SEQ ID NO: 1. The specification only provide rudimentary qualities to supernatants and extracts such as stability and the retention and loss of activity in filters as different as 40kDa and 100 kDa. Claim 37 is not limited even to the 40kb

sequence but reads on any proteinaceous insecticidal protein that may be obtained from any species within Xenorhabdus that is encoded by a nucleic acid that may hybridize to SEQ ID NO: 1 under hybridization conditions that have not been specifically defined. One in the art would not know what the structure of such a composition would be based on the general disclosure provided. The specification discloses SEQ ID NO: 1 which corresponds to the cDNA/genomic DNA encoding a proteinaceous pesticidal compound or compounds. The invention is further drawn to encompass proteins that are encoded by gene sequences, sequences that hybridize to SEQ ID NO: 1, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai

Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Since the instant specification provides only a nucleic acid sequence and does not provide any sequences for the proteinaceous compounds of the claims it is the position of the examiner that an adequate written description of the instant invention is lacking.

2. Applicant's arguments filed 5/29/02 have been fully considered but they are not persuasive.

Applicant argues that the rejection of record does not apply to the instant invention since applicant is not claiming a nucleic acid but a protein. It is noted however that applicant claims a protein based on a nucleic acid sequence. No protein sequence has been provided in the claims and the claim are specifically drawn to a protein obtainable from a nucleic acid sequence.

Applicant argues that they have provided a reference sequence SEQ ID NO: 1 which applicant asserts provides toxicity to insects. This is not disputed. Applicant has shown that cellular extracts from organisms expressing SEQ ID NO: 1 have toxicity to insects. The specification does not disclose an isolated pesticidal agent which is an extracellular protein. The instant specification simply does not provide a description of such a protein. Applicant argues that the specification provides a method that may allow one in the art to determine the protein or proteins responsible for the observed activity. It is noted that such a method is not a substitute for a description of the claimed protein. Applicant argues that their subsequent work provides evidence that the specification provides a written description of the invention. It is noted that the publication appears to indicate that the specification , as filed, clearly did not provide a description of the claimed invention since it appears that much experimentation was performed to determine what protein of many potential proteins and further combinations thereof provided for insecticidal activity. It is noted that applicant subsequent work states at page 2067 "[t]he high level of expression of the xptA1 (which, for example, has not been disclosed in the instant specification) gene from the bacteriophage P_L promoter may be responsible for our ability to detect insecticidal activity for this single toxin". This statement is made in the context that it is typically for the insecticidal activity to be dependent from more than one protein. The instant specification does not disclose the combination of any protein for toxicity and clearly does not disclose using the bacteriophage P_L promoter to detect activity of the xptA1 protein. Furthermore it is not clear from applicant subsequent work that the toxic proteins function via the oral route.

In regard to applicant citation of issue patents in support of written description it is noted that patent applications are each determined one their own merits.

3. Claims 37-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of culture medium and cells per se of the Xenorhabdus exemplified as insecticidal compositions, does not reasonably provide enablement for the scope instantly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The instant invention is broadly drawn to a pesticidal agent which is an extracellular protein from an Xenorhabdus species which is encoded by SEQ ID NO: 1 or is a variant thereof and methods of killing or controlling insect pests via such agents.

The instant specification describes the use of cells and supernatant to kill insects. The instant specification does not disclose the killing of any insect via the ingestion of a proteinaceous compound per se but only shows inhibition of growth and death via cells per se and from supernatant. The instant specification does not provide one in the art with guidance for what specific agent is responsible for the death of insects but teaches only that within a 40kb DNA something or things is encoded that causes death of insects. The instant specification does not show any "adaption" of a compound for oral delivery but only shows the "oral delivery" of

cells per se and supernatant from cells. One in the art would not know how to adapt a proteinaceous compound based on the disclosure of the instant application other than delivering cells per se or supernatant form cells. The specification, for example, indicates that this sequence may contain more than one protein coding sequence that may be insecticidal either alone or when presented together (see page 3, lines 10-15). The specification does not provide one in the art what the coding sequence may be within this large piece of DNA or what the sequence or structure of the protein or proteins is/are or whether there are in fact two or more proteins that may or may not be needed to provide for an insecticidal activity. The specification only provide rudimentary qualities to supernatants and extracts such as stability and the retention and loss of activity in filters as different as 40kDa and 100 kDa. It is unclear from the disclosure what specific compound or combination of compounds is responsible for the insecticidal activity observed from the application of supernatant or cells per se. The instant specification doe not point with any particularity to any specific compounds such as those that are claimed. One in the art would be required to make that determination in the practice of the instant invention. Claim 37 is not limited even to the 40kb sequence but reads on any proteinaceous insecticidal protein that may be obtained from any species within Xenorhabdus that is encoded by a nucleic acid that may hybridize to SEQ ID NO: 1 under hybridization conditions that have not been specifically defined. One in the art would not know what the structure of such a composition would be based on the general disclosure provided One in the art would be required to perform undue trial and error experimentation to practice the instant invention. The Quantity of experimentation would

include, for example, The determination of methods to "adapt proteinaceous compounds" for oral administration, determine what protein or proteins provide for pesticidal properties (for example is it one protein or a combination of two or more, does the protein itself provide toxicity of does the protein convert some substrate into a toxic substance and is this substrate from the cells per se or from the medium provided for growth?). The specification teaches one in the art how to use a cell per se and how to use a supernatant in the killing of insect pests. The instant specification does not teach one how to make or use any specific pesticidal proteins as is instantly claimed.

4. Applicant's arguments filed 5/29/02 have been fully considered but they are not persuasive.

Applicant argues that the instant claim have omitted the adapted for oral activity, but this would appear to still be embraced in the claims. Applicant argues that the oral activity of the specific toxins has been retained even via the transfer to *E.coli.* The instant specification does not disclose the use of any toxins per se but the use of cells and supernatant in the killing of insects. The specification does not disclose an isolated pesticidal agent which is an extracellular protein. The instant specification simply does not provide a description of such a protein and how to use such a protein such that it would be toxic upon oral administration, for example. It is noted that applicant subsequent work (cited in applicants response filed 5/29/02) states at page 2067 "[t]he high level of expression of the xptA1 (which, for example, has not been disclosed in the instant specification) gene from the bacteriophage P_L promoter may be responsible for our ability to

detect insecticidal activity for this single toxin". This statement is made in the context that it is typically for the insecticidal activity to be dependent from more than one protein. The instant specification does not disclose the combination of any protein for toxicity and clearly does not disclose using the bacteriophage P_L promoter to detect activity of the xptA1 protein. It is clear that one in the art would clearly have been required to perform undue trial end error experimentation to find and characterize the claimed invention. It is noted that the instant specification appears to provide a starting point for experimentation to find the claimed invention where the instant specification fails to described or provide sufficient guidance for the claimed invention. Furthermore it is not clear from applicant subsequent work that the toxic proteins function via the oral route.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

6. Claims 41 and 46-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Dudney (US 5,616,318). This rejection has been withdrawn.

7. Those rejections set forth in the Official Action mailed 11/20/02 and not repeated herein are withdrawn.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean McGarry whose telephone number is (703) 305-7028. The examiner can be reached M-Th 6:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. Papers should be faxed to Art Unit 1635 via the PTO Technology Center Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see C.F.R. 1.6(d)). The Art Unit 1635 FAX number is (703) 308-4242 or (703) 305-3014. NOTE: If Applicant **does** submit a paper by Fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Sean McGarry

August 9, 2002

SEAN McGARRY
PRIMARY EXAMINER
1635